United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program

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Title: USDA/AMS Quality Assurance Program		
Revision: 01	Replaces: 08/15/03	Effective: 05/01/06

1. Purpose

To establish requirements for the USDA/AMS Microbiological Data Program (MDP) quality assurance program.

2. Scope

This Standard Operating Procedure (SOP) shall be followed by the USDA/AMS Monitoring Programs Office (MPO), Manassas, VA.

3. Outline of Procedure

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4. References

- MDP Federal/State Meeting, Arlington, VA, May 15-16, 2003
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, July 1, 2005

5. Specific Procedures

5.1. Description

5.1.1. USDA/AMS shall ensure that a quality assurance (QA) program is in place to monitor overall QA for sampling technical, and database functions. The Technical Director shall have overall responsibility for assuring USDA/AMS management that facilities, equipment, personnel, methods, practices, records, and controls of the program are in conformance with the plans and SOPs issued by USDA/AMS and all applicable Good Laboratory Practices (GLP) regulations.

5.1.2. Specific QA functions shall be assigned by the Technical Director, in consultation with the Program Administrative Director, to appropriate sampling, technical, and database staff.

5.1.3. Appropriate MDP records shall be maintained. Documents shall be maintained in a secure manner with reasonable environmental protection from deterioration for the life of the program. Electronic and hardcopy records shall be centrally maintained according to established MPO procedures. Maintenance shall be in an organized and systematic manner which allows accessibility by authorized staff.

5.1.4. The Technical Director, in consultation with the Program Administrative Director, shall appoint an individual to serve as the MDP Document Control Officer. The Document Control Officer shall serve as the focal point for selected documents, reports, and correspondence pertaining to program quality control (QC) and/or QA issues.

5.2. Files and Records

5.2.1. The Technical Director shall assure that copies of the following documents are maintained in the centralized files:

5.2.1.1. MDP annual, semi-annual, or quarterly plans including the schedule of samples, organisms, and commodities to be tested.

5.2.1.2. Schedule of USDA/AMS sampling and laboratory reviews and report submissions. This shall include the dates reviews were made and the dates findings were reported to appropriate individuals.

5.2.1.3. Special project status reports prepared by USDA/AMS liaison microbiologists.

5.2.2. The following documents are maintained in the centralized files by the assigned sampling or laboratory liaison(s):

5.2.2.1. Authorizations for deviations from the USDA/AMS SOPs.

5.2.2.2. Semi-annual internal laboratory QA status and yearly audit reports.

5.2.2.3. Sampling and laboratory review reports.

5.2.3. The following documents are maintained in the centralized files by the Document Control Officer:

5.2.3.1. Laboratory validation data review reports.

5.2.3.2. USDA/AMS SOPs, including administrative, sampling, laboratory, and USDA/AMS internal SOPs.

5.3. Method Validation

5.3.1. All laboratories are required to perform method validation studies according to validation protocols supplied by USDA/AMS.

5.3.2. Studies shall be submitted to the Technical Director and assigned laboratory liaison for review and concurrence.

5.3.3. The Document Control Officer shall track and file all validation study reports to ensure that all required studies are performed by all applicable laboratories.

5.3.4. The Document Control Officer shall promptly communicate to the Technical Director delays in study reports submission.

5.4. Proficiency Testing (PT) Program

5.4.1. All MDP laboratories analyzing routine MDP samples are required to participate in the PT program.

5.4.2. The Technical Director is responsible for management of the PT program. A PT schedule will be included in the MDP semi-annual program plans.

5.4.3. The Technical Director shall assure that PT samples are delivered on schedule and reports are prepared in a timely fashion and distributed to appropriate individuals. Distribution shall include the Administrative Director, participating laboratory TPMs and QAUs, and MPO laboratory liaisons

5.5. Technical Advisory Group (TAG)

5.5.1. The group shall be comprised of selected members of participating laboratories and shall address program technical and QA issues/concerns.

5.5.2. The USDA/AMS Technical Director shall serve as liaison to the USDA/AMS TAG.

5.5.3. A Chairperson will be elected each year and shall have sign-off responsibility for the USDA/AMS program SOPs, with the exception of administrative SOPs, developed or revised during their term.

5.6. SOPs and Deviations from SOPs

5.6.1. The MDP Sampling Manager is responsible for preparing/revising and organizing and carrying out the SOP review and approval process for all program sampling SOPs.

5.6.2. The Technical Director is responsible for assigning preparation/revision of all program laboratory SOPs to MPO microbiologists/laboratory liaisons and is responsible for preparing/revising MDP administrative procedures and for assuring that internal SOPs are prepared/revised.

5.6.3. The Technical Director shall ensure that any authorization for deviations from approved program plans or USDA/AMS MDP SOPs does not compromise data integrity and that precise and technically accurate documentation of such errors/deviations is maintained.

5.6.4. The Document Control Officer is responsible for organizing the SOP review and approval process for all laboratory, administrative, and internal SOPs.

5.6.5. The Document Control Officer is responsible for maintaining all current and historical USDA/AMS SOP hardcopy and electronic files according to established MPO procedures. Refer to MDP-ADMIN-07, section 5.3, for specific details.

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Revision 01	April 2006	Monitoring Programs Office

- Updated to conform with current MPO organization
- Modified format for consistency with other SOPs

Original	May 2003	Monitoring Programs Office

- Established requirements for USDA/AMS MDP QAU